



12-30-05

IFW

1648

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Pau et al.

Serial No.: 09/722,867

Filed: November 27, 2000

For: PRODUCTION OF VACCINES

Confirmation No.: 4248

Examiner: M. Hill

Group Art Unit: 1648

Attorney Docket No.: 2578-4626US

NOTICE OF EXPRESS MAILING

Express Mail Mailing Label Number: EL994842877US

Date of Deposit with USPS: December 29, 2005

Person making Deposit: Diane Sanders

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In compliance with the duty to disclose information material to patentability pursuant to 37 C.F.R. § 1.56, it is respectfully requested that this Supplemental Information Disclosure Statement be entered and the documents listed on attached Form PTO/SB/08 be considered by the Examiner and made of record.

Pursuant to 37 C.F.R. § 1.98(d), a copy of any patent, publication or other information listed in the Information Disclosure Statement is not required to be provided if it was previously cited by or submitted to the office in a prior application, provided that the prior application is properly identified in the statement and relied upon for an earlier filing date under 35 U.S.C. § 120.

01/03/2006 HDEHES1 00000112 09722867

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Accordingly, no copy of information marked with a pound sign (#) is enclosed because it was previously cited or submitted to the patent office in a prior application which is properly identified, and is relied upon for an earlier filing date. The references are as follows:

U.S. Patent Documents

<u>U.S. Patent No.</u>	<u>Publication Date</u>	<u>Patentee</u>
#US - 6,878,549 B1	04-12-2005	Vogels et al.

Foreign Patent Documents

<u>Document No.</u>	<u>Publication Date</u>	<u>Patentee</u>
#EP 0 833 934 B1	04-08-1998	Fallaux et al.

Other Documents

#ALKHATIB et al., "Expression of Bicistronic Measles Virus P/C mRNA by Using Hybrid Adenovirus: Levels of C Protein Synthesized In Vivo Are Unaffected by the Presence or Absence of the Upstream P Initiator Codon," Journal of Virology, November 1988, pp. 4059-4068, Vol. 62, No. 11.

#ALKHATIB et al., "High-Level Eucaryotic In Vivo Expression of Biologically Active Measles Virus Hemagglutinin by Using an Adenovirus Type 5 Helper-Free Vector System," Journal of Virology, August 1988, pp. 2718-2727, Vol. 62, No. 8.

#BERG et al., High-Level Expression of Secreted Proteins from Cells Adapted to Serum-Free Suspension Culture, Research Report, 1993, pp. 972-78, Vol. 14, No. 6.

#BROWN et al., "Evaluation of Cell Line 293 for Virus isolation in Routine Viral Diagnosis," Journal of Clinical Microbiology, April 1986, pp. 704-708, Vol. 23, No. 4.

#BUKREYEV et al., "Recombinant Respiratory Syncytial Virus from Which the Entire SH Gene Has Been Deleted Grows Efficiently in Cell Culture and Exhibits Site-Specific Attenuation in the Respiratory Tract of the Mouse," Journal of Virology, December 1997, pp. 8973-8982, Vol. 71, No. 12.

#CARAVOKYRI et al., "Constitutive Episomal Expression of Polypeptide IX (pIX) in a 293-Based Cell Line Complements that Deficiency of pIX Mutant Adenovirus Type 5," Journal of Virology, November 1995, pp. 6627-6633, Vol. 69, No. 11.

#Certificate of deposit of the PER.C6 cell line (ECACC deposit under number 96022940).

#CICCARONE et al., "Lipofectamine 2000 Reagent for Transfection of Eukaryotic Cells," Focus, 1999, pp. 54-55, Vol. 21, No. 2.

#COTE et al., Serum-Free Production of Recombinant Proteins and Adenoviral Vectors by 293SF-3F6 Cells, Biotechnology and Bioengineering, September 5, 1998, pp. 567-75, Vol. 59, No. 5.

#DuBRIDGE et al., "Analysis of Mutation in Human Cells by Using an Epstein-Barr Virus Shuttle System," Molecular and Cellular Biology, January 1987, pp. 397-387, Vol. 7, No. 1.

#FALLAUX et al., Characterization of 911: A New Helper Cell Line for the Titration and Propagation of Early Region 1-Deleted Adenoviral Vectors, Human Gene Therapy, January 20, 1996, pp. 215-222, Vol. 7.

#Figure 1 submitted by Opponent I.

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#GARNIER et al., Scale-up of the adenovirus expression system for the production of recombinant protein in human 293S cells, Cytotechnology, 1994, pp. 145-55, Vol. 15.

#GenBank Accession No. X02996.1, 1993, "Adenovirus type 5 left 32% of the genome."

#GIBCO cell culture, A Guide to Serum-Free Cell Culture, www.invitrogen.com.

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#Interlocutory Decision of the Opposition Division of 21 July 2003 in the case EP 0 695 351(European application 94 913 174.2)

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#LUTZ et al., "The Product of the Adenovirus Intermediate Gene IX Is a Transcriptional Activator," Journal of Virology, July 1997, pp. 5102-5109, Vol. 71, No. 7.

#MANSERVIGI et al., "Protection from Herpes Simplex Virus Type 1 Lethal and Latent Infections by Secreted Recombinant Glycoprotein B Constitutively Expressed in Human Cells with a BK Virus Episomal Vector," Journal of Virology, January 1990, pp. 431-436, Vol. 64, No.1.

#Marketing Authorization and Scientific Discussion for Xigris.

#MASSIE et al., Improved Adenovirus Vector Provides Herpes Simplex Virus Ribonucleotide Reductase R1 and R2 Subunits Very Efficiently, Biotechnology, June 1995, pp. 602-08, Vol. 13.

#NEUMANN et al., "Generation of influenza A viruses entirely from cloned cDNAs," Proc. Natl. Acad. Sci., August 1999, pp. 9345-9350, Vol. 96.

#Notice of Opposition to a European Patent for 1 161 548.

#Opposition against European patent 1 108 878 B1 filed October 5, 2005 in the name and on behalf of CEVEC Pharmaceuticals GmbH.

#Opposition against European patent 1 161 548 B1 filed November 16,2005, in the name and on behalf of CEVEC Pharmaceutical GmbH.

#Opposition against European patent 1108787 filed October 5, 2005 in the name and on behalf of Probiogen AG.

#ORY et al., "A stable human-derived packaging cell line for production of high titer retrovirus/vesicular stomatitis virus G pseudotypes," Proc. Natl. Acad. Sci., October 1996, pp. 11400-11406, Vol. 93.

#PARKINSON et al., "Stable Expression of a Secretable Deletion Mutant of Recombinant Human Thrombomodulin in Mammalian Cells," The Journal of Biological Chemistry," 25 July 1990, pp. 12602-12610, Vol. 265, No. 21.

#PLESCHKA et al., "A Plasmid-Based Reverse Genetics System for Influenza A Virus," Journal of Virology, June 1996, pp. 4188-4192, Vol. 70, No. 6.

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#U.S. Department of Health and Human Services, Public Health Service, Food and drug Administration, Center for Biologics Evaluation and Research, International Association for Biologicals, National Institute of Allergy and Infectious Diseases, National Vaccine Program Office, World Health Organization, Evolving Scientific and Regulatory Perspectives on Cell Substrates for Vaccine Development, Workshop, Friday, 10 September 1999 (visited 30.09.2005)
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Serial No.: 09/722,867

#YAN et al., Novel Asn-linked oligosaccharides terminating in GalNAcbeta(1-4)[Fucalpha(1-3)]GlcNAcbeta(1-) are present in recombinant human Protein C expressed in human kidney 293 cells, Glycobiology, 1993, pp. 597-608, Vol. 3. No. 6.

#YEAGER et al., Constructing immortalized human cell lines, Current Opinion Biotechnology, 1999, pp. 465-69, Vol. 10.

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#Pursuant to 37 C.F.R. § 1.98(d), copies of the previously identified patents are not being provided since they were previously cited by or submitted to the Office in the following prior application:

Serial No.: 09/449,854

Filed: November 26, 1999

For: PRODUCTION OF VACCINES, which application is being relied upon for an earlier filing date under 35 U.S.C. § 120.

In compliance with the duty to disclose information material to patentability pursuant to 37 C.F.R. § 1.56, Applicants hereby identify the following listed copending applications naming a common inventor(s):

Attorney Docket No.: 2578-4240US
Serial No.: 09/449,854
Filed: 11/26/1999
Title: PRODUCTION OF VACCINES

Attorney Docket No.: 2578-4843US
Serial No.: 09/843,894
Filed: 4/27/2001
Title: AAV VECTOR PRODUCTION

Attorney Docket No.: 2578-3982.3US
Serial No.: 10/783,510
Filed: 2/20/2004
Title: MEANS AND METHODS FOR FIBROBLAST-LIKE OR MACROPHAGE-LIKE CELL TRANSDUCTION

Attorney Docket No.: 2578-4038.2US
Serial No.: 10/234,007
Filed: 9/3/2002
Title: RECOMBINANT PROTEIN PRODUCTION IN A HUMAN CELL

Serial No.: 09/722,867

Attorney Docket No.: 2578-4038.3US
Serial No.: 10/790,562
Filed: 3/1/2004
Title: RECOMBINANT PROTEIN PRODUCTION IN A HUMAN CELL

Attorney Docket No.: 2578-4451.1US
Serial No.: 10/196,688
Filed: 7/15/2002
Title: ADENO-ASSOCIATED VIRUS AND ADENOVIRUS CHIMERIC
RECOMBINANT VIRUSES USEFUL FOR THE INTEGRATION
OF FOREIGN GENETIC INFORMATION INTO CHROMOSOMAL
DNA OF TARGET CELLS

Attorney Docket No.: 2578-6158US
Serial No.: 10/698,086
Filed: 10/30/2003
Title: METHODS FOR THE IDENTIFICATION OF ANTIVIRAL
COMPOUNDS

Attorney Docket No.: 2578-6448US
Serial No.: 10/497,832
Filed: 1/10/2005
Title: PRODUCTION OF VIRUSES, VIRAL ISOLATES AND VACCINES

Attorney Docket No.: 2578-4626.1US
Serial No.: 11/271,368
Filed: 11/11/2005
Title: PRODUCTION OF VACCINES

Attorney Docket No.: 2578-6448.1US
Serial No.: 11/026,518
Filed: 12/30/2004
Title: OVEREXPRESSION OF ENZYMES INVOLVED IN
POST-TRANSLATIONAL PROTEIN MODIFICATIONS IN
HUMAN CELLS

Attorney Docket No.: 2578-6827US
Serial No.: 11/110,517
Filed: 4/20/2005
Title: VACCINES AGAINST WEST NILE VIRUS

Serial No.: 09/722,867

Attorney Docket No.: 2578-6845US
Serial No.: 11/105,725
Filed: 4/14/2005
Title: NEW SETTINGS FOR RECOMBINANT ADENOVIRAL-BASED
VACCINES

Attorney Docket No.: 2578-6964US
Serial No.: 11/102,073
Filed: 4/8/2005
Title: COMPOSITIONS OF ERYTHROPOIETIN ISOFORMS
COMPRISING LEWIS-X STRUCTURES AND HIGH SIALIC ACID
CONTENT

Attorney Docket No.: 2578-6979US
Serial No.: 11/143,986
Filed: 6/2/2005
Title: RECOMBINANT VIRAL-BASED MALARIA VACCINES

Attorney Docket No.: 2578-7508US
Serial No.: 11/256,352
Filed: 10/21/2005
Title: PRODUCTION OF VACCINES

This Supplemental Information Disclosure Statement is filed after the mailing date of the first Office Action on the merits. The fee pursuant to 37 C.F.R. § 1.17(p) is enclosed.

Serial No.: 09/722,867

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Allen C. Turner', with a stylized, flowing script.

Allen C. Turner

Registration No. 33,041

Attorney for Applicant(s)

TRASKBRITT, P.C.

P.O. Box 2550

Salt Lake City, Utah 84110-2550

Telephone: 801-532-1922

Date: December 28, 2005

ACT/alb

Enclosures: Form PTO/SB/08

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet	1	of	5
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Complete if Known

Application Number	09/722,867
Filing Date	November 27, 2000
First Named Inventor	Pau et al.
Group Art Unit	1648
Examiner Name	M. Hill
Attorney Docket Number	2578-4626US

U.S. PATENT DOCUMENTS

[illegible]

FOREIGN PATENT DOCUMENTS

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Signature**

Date
Considered

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¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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**INFORMATION DISCLOSURE
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Sheet 2 of 5

Complete if Known

Application Number	09/722,867
Filing Date	November 27, 2000
First Named Inventor	Pau et al.
Group Art Unit	1648
Examiner Name	M. Hill
Attorney Docket Number	2578-4626US

NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		#ALKHATIB et al., "Expression of Bicistronic Measles Virus P/C mRNA by Using Hybrid Adenovirus: Levels of C Protein Synthesized In Vivo Are Unaffected by the Presence or Absence of the Upstream P Initiator Codon," Journal of Virology, November 1988, pp. 4059-4068, Vol. 62, No. 11.	
		#ALKHATIB et al., "High-Level Eucaryotic In Vivo Expression of Biologically Active Measles Virus Hemagglutinin by Using an Adenovirus Type 5 Helper-Free Vector System," Journal of Virology, August 1988, pp. 2718-2727, Vol. 62, No. 8.	
		#BERG et al., High-Level Expression of Secreted Proteins from Cells Adapted to Serum-Free Suspension Culture, Research Report, 1993, pp. 972-78, Vol. 14, No. 6.	
		#BROWN et al., "Evaluation of Cell Line 293 for Virus isolation in Routine Viral Diagnosis," Journal of Clinical Microbiology, April 1986, pp. 704-708, Vol. 23, No. 4.	
		#BUKREYEV et al., "Recombinant Respiratory Syncytial Virus from Which the Entire SH Gene Has Been Deleted Grows Efficiently in Cell Culture and Exhibits Site-Specific Attenuation in the Respiratory Tract of the Mouse," Journal of Virology, December 1997, pp. 8973-8982, Vol. 71, No. 12.	
		#CARAVOKYRI et al., "Constitutive Episomal Expression of Polypeptide IX (pIX) in a 293-Based Cell Line Complements that Deficiency of pIX Mutant Adenovirus Type 5," Journal of Virology, November 1995, pp. 6627-6633, Vol. 69, No. 11.	
		#Certificate of deposit of the PER.C6 cell line (ECACC deposit under number 96022940).	
		#CICCARONE et al., "Lipofectamine 2000 Reagent for Transfection of Eukaryotic Cells," Focus, 1999, pp. 54-55, Vol. 21, No. 2.	
		#COTE et al., Serum-Free Production of Recombinant Proteins and Adenoviral Vectors by 293SF-3F6 Cells, Biotechnology and Bioengineering, September 5, 1998, pp. 567-75, Vol. 59, No. 5.	
		#DuBRIDGE et al., "Analysis of Mutation in Human Cells by Using an Epstein-Barr Virus Shuttle System," Molecular and Cellular Biology, January 1987, pp. 397-387, Vol. 7, No. 1.	
		#FALLAUX et al., Characterization of 911: A New Helper Cell Line for the Titration and Propagation of Early Region 1- Deleted Adenoviral Vectors, Human Gene Therapy, January 20, 1996, pp. 215-222, Vol. 7.	

Examiner
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Sheet 3 of 5

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Application Number	09/722,867
Filing Date	November 27, 2000
First Named Inventor	Pau et al.
Group Art Unit	1648
Examiner Name	M. Hill
Attorney Docket Number	2578-46261US

NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		#Figure 1 submitted by Opponent I.	
		#GALLIMORE et al., Transformation of Human Embryo Retinoblasts with Simian Virus 40, Adenovirus and ras Oncogenes, Anticancer Research, 1986, pp. 499-508, Vol.6.	
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		#GIBCO cell culture, A Guide to Serum-Free Cell Culture, www.invitrogen.com.	
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		#GRAHAM et al., "Growth of 293 cells in suspension culture," J Gen Virol, March 1987, pp. 937-940, Vol. 68.	
		#GRAHAM, Cell Lines, Promochem (visited 04.10.2005) <http://www.lgcpromochem-atcc.com/SearchCatalogs/longview.cfm?view=ce,1146678...>.	
		#HOLZER et al., "Construction of a Vaccinia Virus Deficient in the Essential DNA Repair Enzyme Uracil DNA Glycosylase by a Complementing Cell Line," Journal of Virology, July 1997, pp. 4997-5002, Vol. 71, No. 7.	
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Application Number	09/722,867
Filing Date	November 27, 2000
First Named Inventor	Pau et al.
Group Art Unit	1648
Examiner Name	M. Hill
Attorney Docket Number	2578-46261 US

NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		#LOPEZ et al., Efficient production of biologically active human recombinant proteins in human lymphoblastoid cells form integrative and episomal expression vectors, Gene, 1994, pp. 285-91, Vol. 148.	
		#LUTZ et al., "The Product of the Adenovirus Intermediate Gene IX Is a Transcriptional Activator," Journal of Virology, July 1997, pp. 5102-5109, Vol. 71, No. 7.	
		#MANSERVIGI et al., "Protection from Herpes Simplex Virus Type 1 Lethal and Latent Infections by Secreted Recombinant Glycoprotein B Constitutively Expressed in Human Cells with a BK Virus Episomal Vector," Journal of Virology, January 1990, pp. 431-436, Vol. 64, No.1.	
		#Marketing Authorization and Scientific Discussion for Xigris.	
		#MASSIE et al., Improved Adenovirus Vector Provides Herpes Simplex Virus Ribonucleotide Reductase R1 and R2 Subunits Very Efficiently, Biotechnology, June 1995, pp. 602-08, Vol. 13.	
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		#Opposition against European patent 1 108 878 B1 filed October 5, 2005 in the name and on behalf of CEVEC Pharmaceuticals GmbH.	
		#Opposition against European patent 1 161 548 B1 filed November 16, 2005, in the name and on behalf of CEVEC Pharmaceutical GmbH.	
		#Opposition against European patent 1 108 787 filed October 5, 2005 in the name and on behalf of Probiogen AG.	
		#ORY et al., "A stable human-derived packaging cell line for production of high titer retrovirus/vesicular stomatitis virus G pseudotypes," Proc. Natl. Acad. Sci., October 1996, pp. 11400-11406, Vol. 93.	

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Sheet 5 of 5

Complete if Known

Application Number	09/722,867
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Examiner Name	M. Hill
Attorney Docket Number	2578-46261JS

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		#PARKINSON et al., "Stable Expression of a Secretable Deletion Mutant of Recombinant Human Thrombomodulin in Mammalian Cells," The Journal of Biological Chemistry, 25 July 1990, pp. 12602-12610, Vol. 265, No. 21.	
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Examiner Signature		Date Considered	

#Pursuant to 37 C.F.R. § 1.98(d), copies of the previously identified patents are not being provided since they were previously cited by or submitted to the Office in the following prior application:

Serial No.: 09/449,854

Filed: November 26, 1999

For: PRODUCTION OF VACCINES, which application is being relied upon for an earlier filing date under 35 U.S.C. § 120.

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